Maryland Board of Pharmacy Public Meeting Minutes

Date: November 16, 2011

Name	Title	Present	Absent	Present	Absent
Bradley-Baker, L.	Commissioner	✓		4	1
Chason, D.	Commissioner	✓		5	0
Finke, H.	Commissioner	✓		5	0
Gavgani, M. Z.	Commissioner	✓		3	2
Hammonds, S.	Commissioner		✓	2	1
Handelman, M.	Commissioner	✓		4	1
Israbian-Jamgochian, L.	Commissioner/Treasurer	✓		5	0
Matens, R.	Commissioner	✓		4	1
Souranis, M.	Commissioner//President	✓		5	0
St. Cyr, II, Z. W.	Commissioner	✓		5	0
Taylor, D.	Commissioner	✓		5	0
Taylor, R.	Commissioner/Secretary	✓		3	2
Bethman, L.	Board Counsel	✓		5	0
Felter, B.	Staff Attorney	✓		5	0
Naesea, L.	Executive Director	✓		4	0
Wu, Y.	Compliance Manager	✓		4	1
Daniels, D	Licensing Manager	✓		5	0
Gaither, P.	Administration and Public Support Manager	√		4	1
Jeffers, A.	Legislation/Regulations Manager	✓		5	0

Subject	Responsible Party		Action Due Date	
		Discussion	(Assigned To)	Results
I. Executive	A. M. Souranis,	Members of the Board with a conflict of interest relating to any item		
Committee	Board	on the agenda are advised to notify the Board at this time or when		
Report(s)	President	the issue is addressed in the agenda.		
		 M. Souranis called the Public Meeting to order at 9:54 a.m. M. Souranis requested all meeting attendees to introduce themselves and to remember to sign the guest log and indicate whether they would like continuing education credits before they leave the meeting. 		
		3. M. Souranis reported that all guests will be given packets of materials so that they can follow the meeting's agenda		

Subject	Responsible Party	D: :	Action Due Date	D 14
	B. R. Taylor Secretary	items and discussions. Guests are requested to return the draft packets when they leave the meeting. 4. Members of the Board with any conflict of interest relating to any item on the agenda were advised to notify the Board. 5. Review and Approval of Miunutes of October 19, 2011: "Old Business," should be changed to "new business"	6. Motion by R, Matens to accept October 19, 2011 minutes as revised	Results 6. Motion approved
II. Executive Director Report	A. L. Naesea	 Operations Update: Executive Director L. Naesea introduced Arpit Mehta, pharmacy student from LECOM School of Pharmacy who will be on rotation at BOP through December, 2011, and a new hire, Stephen J. Holmes, Board Executive Assistant Meeting Updates: L. Naesea summarized the NABP District Meeting attended by herself and Commissioner Lenna Israbian-Jamgochian on October 20 through 22, 2011. Board of Pharmacy Retreat Report: L. Naesea summarized the retreat attended by entire staff and all commissioners for BOP on November 2 & 3, 2011 and noted that the BOP will be implementing the 30, 60 and 90 day recommendations as presented in final report of retreat from the retreat facilitator L. Naesea summarized the 10 year Sunset Review Evaluation of the BOP, dated October, 2011. 		
B. Administration and Public Support	B. P. Gaither, Manager	1. Personnel Updates -: Vacancies and Recruits- : a) Part time Pharmacist Inspector - Interviews are expected to take place within the next 4 weeks		
		b)Permanent Office Secretary Receptionist – The position is still in		

recruitment and expected to be filled before the end of the year. c)Permanent Office Secretary Licensing – The position is still in review and expected to be filled before the end of the year. 2. Contract to Manage MIS Project – A candidate has been tentatively selected and the Board is awaiting approval from the department. The anticipated start date is in late November – and should extend through April 2012. b) PEAC Contract – The contract will expire April 30, 2012. Ms. Gaither is working with the Compliance Unit and Board members in reviewing requirements for the renewal contract. c) RCI Help Desk contract – The contract will expire April 30, 2012. Ms. Gaither is working with the Compliance Unit and Board members in reviewing requirements for the renewal contract. c) RCI Help Desk contract – The contract will be revised to reflect fewer printed copies ordered since the newsletter will be e-mailed to curolled recipients. C. MIS L. Naesea Database Implementation Project: L. Naesea reported that the BOP is waiting on DHMH to approve the hiring of MIS Project Manager, and decision should be made within one week of the approval. Licensing D. Daniels, Manager Hieraring Unit Updates: Monthly Statistics – October 2011: 8815 Pharmacists 2492 Vaccination certificates approved 9835 Registered Pharmacy Technicians 0 Pharmacy Technicians 10 Pharmacy Technicians 10 Pharmacy Technicians 10 Pharmacy Technicians 11 New drug repositories 11 New drug repositories	Subject	Responsible Party	Discussion	Action Due Date	Dogulto
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E. Compliance	Y. Wu, Manager	1. Inspection Program Report – October 2011: 99 total inspections (92 annual and 7 opening inspections). 1 closing inspection (performed by the Division of Drug Control).		
		2. PEAC Update – October 2011:		
		Tony Tommasello, Executive Director of PEAC reported that PEAC monitored 20 cases, no positive drug screens, and review of ASHP CE program. He presented BOP a with copy of PEAC newsletter dated September, 2011.		
F. Legislation & Regulations	A. Jeffers	A. LEGISLATION:		
Regulations		1) November 9, 2011 Meeting with Senator Joan Carter Conway.		
		Anna Jeffers reported that the Board's Legislative committee met with Senator Carter Conway who has agreed to sponsor a wholesale distributor and a jurisdiction of non-resident pharmacies bills. She is considering also sponsoring a bill on dispenser prescribing.		
		2) DHMH Scope of Practice legislation:		
		Health Occupations Boards – Regulations and Scope of Practice Advisory Committee (See Attachment)		
		Senator Paula Hollinger presented the Department's draft legislation regarding Board regulations and scope of practice issues. She described how the Secretary had been asked by various health occupation boards to intervene on several scope of practice disputes. She described the content of the draft legislation and the purpose and structure of the Advisory Committee. A copy of the draft legislation is attached to the minutes.		
		Board discussion ensued concerning the potential for bias among the Advisory Committee members. Senator Hollinger		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		said that data received by the Advisory Committee members would drive their decisions. LaVerne Naesea pointed out the overall concern that there could be an inherent imbalance on the Advisory Committee if more than two Boards are in dispute over a practice issue.	(mm 8 vm v/	
		Senator Hollinger reiterated the Secretary's three areas of focus for his involvement with the health occupation boards: 1) Customer Service; 2) Resolution of disputes in a timely manner; and 3) Resolution of Scope of Practice issues.		
		3) ANNUAL REPORTS TO THE LEGISLATURE:		
		a) Maryland Board of Pharmacy Prescription Drug Repository Program Sixth Annual Report to the Governor and the General Assembly FINAL DRAFT RxDrugRepReport to GenAssembly 111011	Motion: Practice Committee Second: R. Matens	a. The Board approved submission of the Prescription Drug Repository Program
		b) Maryland Board of Pharmacy Wholesale Distributor Permitting and Prescription Drug Integrity Act Fifth Annual Report to the Governor and the General Assembly		Sixth Annual Report
		FINAL DRAFT Report WholesaleDist Program 2012 111011		b. The Board approved submission of the Wholesale
		B. FEDERAL LEGISLATION:		Distributor Permitting and Prescription Drug
		FYI: News Release on Fed Regs 102111		Integrity Act Fifth Annual Report
		Federal Register-Bath Salts 102111	1. Motion: Practice committee Second: M. Gavgani	1) The Board approved the
		C. REGULATIONS:		revisions for

Subject	Responsible Party		Action Due Date	
2.2.7000		Discussion	(Assigned To)	Results
		1) 10.34.14 Opening and Closing of Pharmacies		submission to the
		Submitted for Board Approval:		Department for sign- off and publication in
		10.34.14 post-signature edits 103111 for Bd Packet		the Maryland Register.
			2. Motion: Practice committee	
		2) 10.34.18 Continuing Education for Pharmacists	Second: D. Chason	2) The Board approved the
		Submitted for Board Approval:		revisions for
		Draft 10.34.18 Cont Ed-Live CEs 110111 MP		submission to the Department for sign-
				off and publication in
				the Maryland Register.
		3) 10.34.23 Pharmaceutical Services to Patients in		The Board also approved submitting
		Comprehensive Care Facilities		the proposal as
		Anticipated to be published December 16, 2011.		Emergency Status.
		4) 10.34.25 Delivery of Prescriptions		
		Published October 21, 2011.		
		5) 10.34.28 Automated Medication Systems		
		Anticipated to be published December 2, 2011.		
		6) 10.34. 32 Pharmacists Administration of Vaccinations		
		Influenza – Emergency Effective Date retroactive to October 1, 2011. Actual Emergency Notice will be published November 18, 2011.		
		Regular proposal published November 4, 2011.		
		Travel Vaccines – Mtg held 8/21/11.		
		7) 10.34.33 Prescription Drug Repository Program		
		Holding off on revisions until the Fed draft proposal is published later this fall.		
		8) 10.34.35 Infusion Pharmacy Services in an Alternate Site Care Environment	8. Date should be March 1, 2012, R. Matens suggested adding to Board	
		Notice of Final Action published November 4, 2011 with an incorrect Effective Date. An Erratum will be published December 2,	newsletter	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		2011 with the correct effective date of March 1, 2012.	(23334234
		9) 10.34.36 Pharmaceutical Services to Patients in Assisted Living Programs, Group Homes, or Correctional Institutions Next meeting is scheduled for Tuesday, November 29, 2011 after Practice.		
		10) 10.13.01 Dispensing of Prescription Drugs by a Licensee		
		Meeting held 101211 with Sara Fidler mediating. (per Senator Carter Conway) Sara will draft regulations with agreed upon issues. She will draft legislation for issues that require a statute change. Should see in early December.		
		11) Point of Care Testing		
		Ratification of e-mail to Shawn Cain commenting on Memorandum regarding Pharmacist-Provided Point of Care Testing.		
		Final lab tests_pharmacists_recommendations_080211_1 Practice Response - Re Pharmacist Lab Testing 110111	11. Motion: Practice Committee Second: H. Finke	11) The Board ratified the Practice Committee responses.
		10.10.03.02 – Letters of Exception		
		10.10.06.02 - Authorization to Request Laboratory Tests		
		10.10.06.12 – Quality Control – Temporary and Mobile		
		Laboratories: General. Laboratory Reg Changes 2 110111 Email response - Re Proposed Lab reg changes 110911.	12. Motion: Practice committee Second: D. Chason	12. Board approved

Subject	Responsible Party		Action Due Date	
~,,		Discussion	(Assigned To)	Results
III. Committee Reports A. Practice Committee	H. Finke, Chair,	Barbara Brannan, UMMC Tech check Tech and dist of non-patient specific meds DRAFT Bd Response - tech check tech	1. Practice Committee moved that response be ratified, motion seconded by M. Gavgani	1. Response RATIFIED
Committee		2) Pam Owens, Johns Hopkins Johns Hopkins - COMAR 10.34.25.06 DRAFT Bd Response - Johns Hopkins COMAR 10.34.25.06	2. Mitra Gavgani and Richard Matens recused themselves from voting on this matter. Practice Committee moved that response be ratified, motion seconded by Z. St Cyr II	2. Response RATIFIED
		3) Bonnie Levin, MedStar Health Instymeds Kiosk - St Mary's Hospital DRAFT Bd Response - Instymeds Kiosk - St Mary's Hospital	3. D. Chason recused. Practice Committee moved that response be ratified, motion seconded by M. Handelman Bonnie Levin made comments to the public	3. Response RATIFIED
		4) Jeff Mesaros, Medco Question Storage of Bulk Solutions DRAFT Bd Response - storage of bulk solutions	4. Practice Committee moved that response be ratified, motion seconded by R. Taylor	4. Vote Tabled. Board requested diagram of storage facility area from Medco.
B. Licensing Committee	D. Chason Chair,	A. Pharmacist Applications: 1.Applicant 2 's license expired 9/30/2011. The license was renewed on time on the website as demonstrated by the payment confirmation number. The credit card failed and the applicant was not asked to send a check. (During this period the Board's system experienced problems in acceptance of credit card payments on-line.	1. – Licensing Committee moved to approve waiver request of Applicant and follow-up regarding procedural review of credit card payments that failed.	1.Motion to approve waiver request APPROVED
		Applicant 1 Requested an extension of NAPLEX score which expired 9/27/2011. MPJE taken on 10/13/2011. The Actual Board	Motion was seconded by Z. St. Cyr, II.	

Subject	Responsible Party		Action Due Date	
Susject	2105 p 01151010 1 111 0 j	Discussion	(Assigned To)	Results
		application expired 10/14/2011. A letter sent by D. James on 10/14/2011 provided details on expiration date of the NAPLEX examination on 9/29/2011. The NAPLEX application was submitted t on 6/21/2011 and notification sent on 6/21/2011. B. Distributor Applications A Distributor applicant requested to use cashier checks instead of trust document irrevocable letter of credit or surety bond. Licensing Committee recommendation is that cash or check will not be considered an approved form of payment	2. – Licensing Committee moved to not extend score/not waive fee and recommend that Applicant 1 reciprocate from DC. Motion seconded by D. Taylor. B. Licensing committee, second by D. Chason	2. Motion to not extend score/not waive fee, but recommend that Applicant 1 reciprocate from DC. APPROVED B. Motion approved
		C. Licensing Procedures Licensing Committee recommends the following sentence be added to all applications, new, renewal, resident, non-resident and waiver pharmacies: "If you or any person or entity having ownership in the pharmacy or any of the license or registered staff ever been subject to ant disciplinary action by any Board of Pharmacy in your state or any other state."	C. Licensing Committee moved that the following sentence be added to all pharmacy applications, new, renewal resident, non-resident, and waiver pharmacies If you or any person or entity having ownership in the pharmacy or any of the license or registered staff ever been subject to ant disciplinary action by any Board of Pharmacy in your state or any other state. Motion seconded by H. Finke, Jr	C. Motion APPROVED
C. Public Relations Committee	L. Bradley-Baker Chair	1. L Bradley-Baker noted that in the future the BOP Newsletter will be made available to the public electronically.		
		2. L. Bradley-Baker presented copy of article entitled "Community		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		pharmacy accreditation begins to take shape" from the November, 2011 issue of Pharmacy Today. Copy attached and to be made a part of these minutes.	(Assigned 10)	Resuits
D. Disciplinary	L. Israbian- Jamgochian Chair	No report.		
E. Emergency Preparedness Task Force	D. Taylor Chair	D. Taylor reported that Maryland has begun the process of reviewing the state RSS plan. Therefore, the Maryland BOP Emergency Preparedness Task Force will be looking at pharmacy involvement and pharmacy parts of that plan to see if any changes need to be made.		
F. Drug Therapy Management	Rodney Taylor Co-Board Representat.	Fink's Pharmacy protocol renewal was approved by the Board of Physician on October 26, 2011 and approval letter sent on November 4, 2011.		
		Much discussion was had concerning the Nov. 9th meeting with joint committee, Physicians and Pharmacists attended by R. Taylor and L. Bradley-Baker, with the focus on the word 'substitution' and/or 'substitute' In the protocol templates.		
IV. Other Business & FYI	M. Souranis	A. M. Souranis stated that at the meeting concerning travel vaccinations the Board of Nursing brought asked the Board is it would consider supporting dispensing legislation for specialty nurses. Much discussion took place. The Legislative and Executive Committees recommend against allowing this, as members felt the Board of Nursing did not demonstrate a need for this, exigent circumstances that would warrant this practice.	A. Legislative & Executive Committees moved that the request by the Board of Nursing be denied. Motion by H. Finke, second by L. Israbian-Jamgochian	A. Motion APPROVED
		B. L. Naesea recommended that the BOP waive late fees for any late Pharmacy renewal applications covering the period of December 1 through December 31, 2011 as notices were not mailed timely to the permit holders.	Second: D Chason	B. Recommendation was APPROVED
V. Adjournment	M. Souranis, Board President	The Public Meeting was adjourned at 11:52am. At 12:05 P.M. M. Souranis convened a Closed Public Session to conduct a medical review of technician applications.	Motion D. Chason, second Z. St Cyr II	

Subject Responsible Par	y Discussion	Action Due Date (Assigned To)	Results
	C. The Closed Public Session was adjourned at 12:50 P.M. Immediately thereafter, M. Souranis convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session.		

ATTACHMENT

J2

By: Department of Health and Mental Hygiene

An Act concerning

Health Occupations Boards - Regulations and Scope of Practice Advisory Committees

For the purpose of authorizing the Secretary of Health and Mental Hygiene

to adopt regulations governing the practices of certain health occupations boards and commissions under certain circumstances; authorizing the Secretary to convene certain advisory committees for certain purposes; requiring certain advisory committees to take into account certain considerations when reviewing scope of practice disputes; requiring certain advisory committees to complete their work within a certain time; specifying that certain advisory committees are subject to certain provisions of law relating to open meetings; requiring certain advisory committees to report their findings to the Secretary; requiring the Secretary to issue a certain report to the General Assembly within a certain time of receiving a certain report of a certain advisory committee; defining a certain term; and generally relating to health occupations boards.

By repealing and reenacting, with amendments,

Article – Health Occupations Section 1-203 Annotated Code of Maryland (2009 Replacement Volume and 2011 Supplement)

By adding to

Article – Health Occupations Section 1-701 through 1-705, under the new subtitle "Subtitle 7. Scope of Practice Advisory Committees" Annotated Code of Maryland (2009 Replacement Volume and 2011 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article - Health Occupations

1-203.

- (a) The power of the Secretary over plans, proposals, and projects of units in the Department does not include the power to disapprove or modify any decision or determination that a board or commission established under this article makes under authority specifically delegated by law to the board or commission.
- (b) The power of the Secretary to transfer staff or functions of units in the Department does not apply to any staff of a board or commission, established under this article, or to any functions that pertain to licensing, disciplinary, or enforcement authority, or to any other authority specifically delegated by law to a board or commission.
- (c) Notwithstanding the provisions of subsection (a) of this section, the Secretary may adopt regulations affecting the scope of practice of a health care practitioner if:
- (1) AGREEMENT IS REQUIRED BY MORE THAN ONE BOARD OR COMMISSION ESTABLISHED UNDER THIS ARTICLE TO ADOPT THE REGULATIONS;
- (2) THE BOARDS OR COMMISSIONS HAVE NOT ADOPTED THE REGULATIONS WITHIN 30 DAYS OF THE DATE THAT THE REGULATIONS WERE REQUIRED UNDER LAW TO HAVE BEEN ADOPTED; AND
- (3) THE SECRETARY HAS APPOINTED A SCOPE OF PRACTICE
 ADVISORY COMMITTEE UNDER SUBTITLE 7 OF THIS TITLE TO REVIEW THE TOPIC OF THE REGULATIONS AND THE SECRETARY HAS REVIEWED THE RECOMMENDATIONS OF THIS COMMITTEE.

SUBTITLE 7. SCOPE OF PRACTICE ADVISORY COMMITTEES.

1-701.

- (A) IN THIS SUBTITLE, "SCOPE OF PRACTICE DISPUTE" MEANS A DISPUTE OVER WHETHER A HEALTH CARE SERVICE MAY BE PROVIDED BY PRACTITIONERS OF A PARTICULAR HEALTH CARE PROFESSION.
- (B) "SCOPE OF PRACTICE DISPUTE" INCLUDES A DISAGREEMENT BETWEEN BOARDS OR COMMISSIONS OVER THE ADOPTION OF REGULATIONS RELATED TO SCOPE OF PRACTICE.

1-702.

THE SECRETARY MAY APPOINT A SCOPE OF PRACTICE ADVISORY COMMITTEE, SUBJECT TO THE PROVISIONS OF THIS SUBTITLE, IN ORDER TO:

- (1) EXAMINE SCOPE OF PRACTICE DISPUTES; AND
- (2) (I) PROVIDE RECOMMENDATIONS TO THE GOVERNOR AND THE GENERAL ASSEMBLY ON THE RESOLUTION OF A SCOPE OF PRACTICE DISPUTE; OR
- (II) PROVIDE RECOMMENDATIONS TO THE SECRETARY UNDER § 1-203(C) OF THIS TITLE.

1-703.

A SCOPE OF PRACTICE ADVISORY COMMITTEE ESTABLISHED UNDER THIS SUBTITLE SHALL CONSIST OF BETWEEN FIVE AND NINE MEMBERS, INCLUDING:

- (1) A MEMBER OF EACH OF THE BOARDS OR COMMISSIONS INVOLVED IN THE SCOPE OF PRACTICE DISPUTE;
- (2) A MEMBER OF A BOARD OR COMMISSION THAT IS NOT INVOLVED IN THE DISPUTE; AND
- (3) TWO MEMBERS OF THE GENERAL PUBLIC WITH EXPERTISE IN SCOPE OF PRACTICE AND EVIDENCE-BASED HEALTH CARE PRACTICE.

1-704.

- (A) IN REVIEWING A SCOPE OF PRACTICE DISPUTE, AN ADVISORY COMMITTEE ESTABLISHED UNDER THIS SUBTITLE SHALL CONSIDER:
- (1) WHETHER THE PROFESSION AT ISSUE HAS EVOLVED
 TOWARD THE ADDITION OF THE NEW SERVICE AND ANY EVIDENCE CONCERNING PRIOR CHANGES IN THE SCOPE OF PRACTICE OF THE PROFESSION;
- (2) WHETHER TRAINING FOR PRACTITIONERS OF THE PROFESSION AT ISSUE IS ADEQUATE FOR THE NEW SERVICE TO BE PERFORMED SAFELY AND EFFECTIVELY;
- (3) WHETHER THERE IS EVIDENCE THAT THE NEW SERVICE, AS
 PERFORMED BY PRACTITIONERS OF THE PROFESSION AT ISSUE, WILL PROMOTE ACCESS TO QUALITY HEALTH CARE; AND
- (4) OTHER FACTORS IDENTIFIED BY THE SECRETARY OR THE ADVISORY COMMITTEE.

- (B) AN ADVISORY COMMITTEE ESTABLISHED BY THE SECRETARY UNDER THIS SUBTITLE SHALL:
- (1) COMPLETE ITS WORK WITHIN 60 DAYS OF BEING CONVENED; AND
 - (2) ISSUE A REPORT ON ITS FINDINGS TO THE

SECRETARY.

(C) MEETINGS OF AN ADVISORY COMMITTEE ESTABLISHED UNDER THIS SUBTITLE ARE SUBJECT TO THE PROVISIONS OF TITLE 10, SUBTITLE 5 OF THE STATE GOVERNMENT ARTICLE.

1-705.

- (A) THE SECRETARY SHALL REPORT TO THE GOVERNOR AND THE GENERAL ASSEMBLY ON THE FINDINGS AND RECOMMENDATIONS OF ANY SCOPE OF PRACTICE ADVISORY COMMITTEE WITHIN 60 DAYS OF RECEIVING THE REPORT OF THE ADVISORY COMMITTEE.
- (B) THE REPORT REQUIRED UNDER THIS SECTION SHALL INCLUDE PLANS FOR REGULATORY ACTION OR LEGISLATIVE RECOMMENDATIONS, AS APPROPRIATE.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect on July 1, 2012.